In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 19-1519V

MARYANN DAUGHERTY, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: June 5, 2024

Daniel James Leeper, St. Petersburg, FL, for Petitioner.

Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM[1]

On October 1, 2019, Maryann Daugherty filed a Petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"), alleging that she suffered a *right-sided* shoulder injury related to vaccine administration ("SIRVA") as the result of an influenza ("flu") vaccine received on October 6, 2016. Petition (ECF No. 1). The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU"). Based on Respondent's opposition and an independent review of the evidence, I conclude that Petitioner has not established the

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

alleged vaccine administration site. Therefore, her Table SIRVA claim is not tenable, and must be dismissed.

I. Procedural History

Over 18 months after the claim's initiation, Petitioner obtained and filed a required record which reflected a contemporaneous, handwritten notation of her *left* (non-injured, non-dominant) arm as the vaccine administration site. Ex. 11 (ECF No. 20). Respondent subsequently objected that Petitioner could not preponderantly establish her alleged site (and secondarily, onset within the 48-hour timeframe required for a Table SIRVA). Resp. Status Report filed July 8, 2021 (ECF No. 24) (signaling his opposition); Rule 4(c) Report filed Mar. 1, 2022 (ECF No. 25).

The parties were afforded a final opportunity to file "briefs and *any additional evidence they wished to have considered*." Scheduling Order filed July 26, 2022 (ECF No. 26) (emphasis added). Only briefing was received. Pet. Response filed Sept. 12, 2022 (ECF No. 27) (hereinafter "Brief"); Respondent's Response filed Nov. 15, 2022 (ECF No. 29) (hereinafter "Response"). The matter is now ripe for adjudication.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[3] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;

[3] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

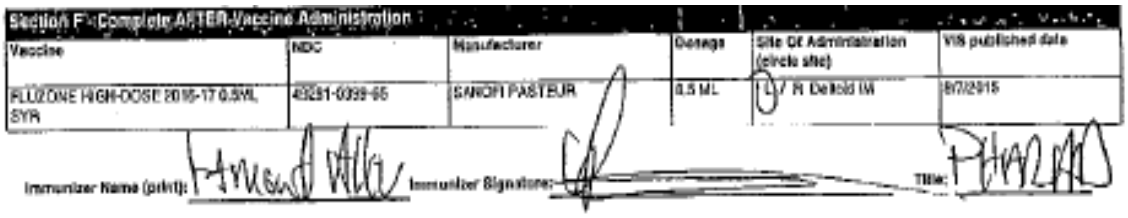
42 C.F.R. § 100.3(c)(10) (2017).

III. Finding of Fact and Conclusions of Law – Vaccine Administration Site

I have reviewed all of the filings submitted by both parties to date. The below summary focuses on the vaccine administration site.

- Medical records from three years prior to the date of vaccination reflect that Petitioner's medical history was non-contributory, and that she is right-handed. *See generally* Exs. 2, 6.

- Petitioner was 75 years old upon receiving the subject Fluzone vaccine on October 6, 2016, at a local Walgreens pharmacy location. The Walgreens "Vaccine Administration Record (VAR) – Informed Consent for Vaccination" form, includes the following section, which indicates a *left-sided* vaccine administration site. Ex. 11 at 2.



Section F - Complete AFTER Vaccine Administration					
Vaccine	NDC	Manufacturer	Dosage	Site Of Administration (circle site)	VIS published date
FLUZONE HIGH-DOSE 2016-17 0.5ML SYR	49281-0399-65	SANOFI PASTEUR	0.5 ML	L / R Deltoid IM	8/7/2015

Immunizer Name (print): Immunizer Signature: Title: PHARM

- On an insurance "payment notice" dated October 17, 2016, a handwritten notation indicates that on October 21, 2016, Petitioner called the insurance provider "questioning overpayment to Walgreens for flu shot," and was informed that the apparent overpayment instead represented an "administration fee for giving shot." Ex. 1 at 4.[4]

[4] Petitioner filed the payment notice as initial proof of receiving the vaccination, Ex. 1, prior to obtaining and filing the contemporaneous vaccine administration record including site, Ex. 11.

- On October 24, 2016, Petitioner followed up with an established orthopedist for her chronic hip and foot pain. No complaints or findings relating to the above vaccination, or the shoulders, were noted. Ex. 6 at 21 – 24.

- Thirty-four (34) days post-vaccination, on November 9, 2016, Petitioner saw her primary care provider ("PCP") Dr. Minnix for a routine six-month follow-up evaluation, and discussed subjects including her right ear, right hip, and hypothyroidism. Ex. 2 at 10. A physical exam was positive for hip tenderness. *Id.* at 11. No complaints or findings relevant to the right shoulder were noted. But Dr. Minnix recorded: "Immunization: Flu3V (Fluzone High Dose), 65 YRS+, NO PRES – ALL PAYORS: 0.5 ML (Dose No:1) on Right Deltoid." *Id.* [5]

- On December 12, 2016, and January 17, 2017, Petitioner attended orthopedics evaluations for her lower extremity complaints. Ex. 6 at 18 – 19, 14 – 17 (ordered chronologically).[6]

- On February 9, 2017 – now four months post-vaccination – Dr. Minnix recorded that Petitioner's complaints included chronic right shoulder pain since "around the time of a flu shot in October of last year." Ex. 2 at 7. The pain was "not in the shoulder joint, but in the proximal humerus near the insertion of the deltoid muscle." *Id.* An exam of the shoulder was unremarkable (specifically noting normal range of motion), except for tenderness at the reported site of vaccination. *Id.* Dr. Minnix assessed non-specific "right arm pain," and planned an x-ray. *Id.*

- On February 15, 2017, an x-ray of the right shoulder visualized a down-sloping acromion" and degenerative changes in the acromioclavicular joint. Ex. 3 at 1. The x-ray indication was "pain in upper third of humerus since flu shot 10/2016." *Id.*

- On May 9, 2017, Dr. Minnix recorded Petitioner's report of ongoing "arm pain which she relates to a flu shot," and her waiver of an orthopedic referral. Ex. 2 at 4 – 5.

- On June 5, 2017, an examiner at Sedgwick Claims Management Services Inc., emailed that based on Petitioner's report of injury persisting for over six months,

[5] Petitioner has not addressed this notation. However, no other evidence suggests that Dr. Minnix administered a *repeat* administration of Fluzone – which involves only one dose. Ex. 2 at 10 – 11; *see also* Food & Drug Administration, *Fluzone Intradermal Quadrivalent 2016 – 2017 Package Insert*, available at https://www.fda.gov/media/90251/download&ved=*2ahUKEwj3z6eKlLGGAxV3M1kFHdm3AQcQFnoECBwQAQ*&usg=AOvVaw0-Gr6zUif05npiuCFHFQY1 (last accessed May 28, 2024).

[6] Subsequent orthopedics records have been reviewed but are omitted from this factual summary.

she would "need to file a claim with the National Vaccine Injury Compensation Program." Ex. 7 at 1.

- In a July 17, 2017, letter addressed to the Vaccine Program, Petitioner reported a right-sided vaccine administration on October 6, 2016, followed by right shoulder pain and weakness. Ex. 8 at 1. Petitioner reported that she had followed up repeatedly with the pharmacy until she was referred to Sedgwick and notified of the Program. *Id.* Petitioner asked the Vaccine Program to "loo[k] into this situation and advis[e] her how to proceed," specifically noting concern about how long the injury would last and potential long-term effects. *Id.*

- In October 2017, upon establishing care with a new PCP, Lauren Natoli, D.O.,[7] Petitioner's complaints included right shoulder pain since her receipt of a flu shot at Walgreens the previous year. Ex. 5 at 21. Dr. Natoli did not record a physical exam or any specific assessment of the shoulder, but recorded that an unnamed lawyer had requested MRIs before proceeding with Petitioner's case. *Id.*

- In November 2017, Dr. Natoli ordered MRIs of the right shoulder and humerus, which visualized a large partial tear of the undersurface of the anterior supraspinatus tendon; a small labrum tear; and moderate subacromial bursitis. Ex. 5 at 31 – 34; *see also id.* at 6 (Dr. Natoli's subsequent note that Petitioner was scheduled for an orthopedic evaluation of her shoulder).

- At a November 14, 2017, initial evaluation, orthopedist David Braun, M.D., recorded Petitioner's history of injury stemming from a flu shot. Ex. 9 at 5; *see also id.* at 7 – 9 (new patient form). On exam, the right shoulder had full ROM, normal strength, and no muscle atrophy – only point tenderness to palpation over the inferior lateral deltoid. *Id.* at 5. In Dr. Braun's view, the MRIs revealed only "slight degenerative changes" and no fracture, dislocation, or structural abnormalities. *Id.* Dr. Braun discussed that he had seen previous cases of flu shots associated with "severe subacromial bursitis," but Petitioner's case was more suggestive of a nerve injury. *Id.* Thus, Dr. Braun referred Petitioner to a colleague specializing in neurology. *Id.*

- On November 28, 2017, the neurologist, Adam DiDio, M.D., recorded a similar history from Petitioner, and an unremarkable exam with the exception of right supraspinatus weakness. Ex. 9 at 2 – 3. Dr. DiDio found no current evidence of brachial neuritis/plexopathy, injury to the axillary nerve (running underneath the

[7] Petitioner's last encounter with Dr. Minnix was in September 2017. It does not address shoulder pain, or any information regarding Petitioner's subsequent switch to a new PCP. Ex. 2 at 1 – 2.

deltoid), or complex regional pain syndrome. *Id.* at 3. He provided a trial of Lidoderm patches and also offered neuropathic pain medications, while deferring to Dr. Braun regarding further orthopedic work-up, such as for a rotator cuff tear. *Id.* But there are no further records from Drs. Braun and DiDio's practice.[8]

- In her October 2019 affidavit, Petitioner attests that that a Walgreens employee administered the subject flu vaccine into her right shoulder. Ex. 10 at ¶ 6. She recalls developing right shoulder pain and difficulty with movement "the same day," which she initially "assumed to be a normal after effect of the vaccine." *Id.* at ¶ 7. After these symptoms persisted for some unspecified period, she "returned to Walgreens on multiple occasions, and made them put it in their records," but the staff instructed Petitioner to "expect pain and discomfort," apply ice, and rub the painful areas. *Id.* at ¶ 8. After those measures did not alleviate her injury, she presented to her PCP Dr. Minnix in February 2017. *Id.* at ¶ 9. Petitioner also attests that her complaints to Walgreens led to her discovery of the Vaccine Program, and to her letter written in July 2017. *Id.* at ¶¶ 8, 21.

- Petitioner avers that there is no additional evidence of her communications with Walgreens, Sedgwick, and/or the Vaccine Program. Pet. Status Report filed Apr. 19, 2021 (ECF No. 21).

The most contemporaneous record – the initial vaccination administration record (Ex. 11 at 2) - is not in Petitioner's favor. In reaction, Petitioner avers that *in general*, "pharmacy employees are not perfect, and mistakes happen when entering information into a record." Brief at 1. However, she does not offer any *case-specific* arguments, or reference any evidence beyond her own affidavit. *Id.* at 1 – 2. In contrast, Respondent contends that the contemporaneous record should receive a high presumption of accuracy, especially as it contains a *handwritten* notation. Rule 4(c) Report at 6 – 7.

Based upon my experience with SIRVA cases (over 2,000 within SPU since my appointment as Chief Special Master, additional cases handled within chambers, and review of opinions issued by other special masters), I observe that it is not unusual for information regarding the vaccine administration site to be incorrect – especially information contained in *computerized* records, which may feature a 'dropdown' menu which may not be updated each time a separate vaccine is administered.[9] Thus, although

[8] I have also considered, but find less relevant to the situs determination, further medical records from the PCP Dr. Natoli. *See generally* Ex. 5.

[9] *See, e.g.*, *Mezzacapo v. Sec'y of Health Servs.*, No. 18-1977, 2021 WL 1940435, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 2021); *Desai v. Sec'y of Health & Human Servs.*, No 14-0811V, 2020 WL 4919777, at *14 (Fed. Cl. Spec. Mstr. July 30, 2020); *Rodgers v. Sec'y of Health & Human Servs.*, No. 18-0559V, 2020 WL

such records are unquestionably the first-generated documents bearing on issues pertaining to situs, they are not per se reliable simply *because* they come first – and in fact the nature of their creation provides some basis for not accepting them at face value. But information which requires *specific action* on the part of the vaccine administrator (often at the very time of administration), such as a handwritten notation on a printed form, generally warrants more significant weight.[10]

Such handwritten notations can be rebutted of course, by additional, case-specific evidence and circumstances. For instance, in one case a petitioner's history of vaccination and subsequent injury in the same shoulder was medically documented just 13 days post-vaccination, and consistently thereafter. That petitioner also explained that she requested vaccination in her non-dominant arm. *Rizvi v. Sec'y of Health & Hum. Servs.*, No. 21-0881V, 2022 WL 2284311 at * 3 (Fed. Cl. Spec. Mstr. May 13, 2022). In another more recent matter, the petitioner's history was medically documented 23 days post-vaccination, and in numerous later records. And the site notation was found on "an otherwise haphazardly-completed form (containing entries listed diagonally and not in the allotted space)" – constituting a specific reason to doubt its reliability. *Toothman v. Sec'y of Health & Hum. Servs.*, No. 22-0207V, 2024 WL 2698520, at *4 (Fed. Cl. Spec. Mstr. Apr. 19, 2024).

Here, Petitioner has not raised any specific reason to question the accuracy of the handwritten notation on the initial vaccination record – and it appears to have been completed correctly (rather than "haphazardly," as in *Toothman*, 2024 WL 2698520, at *4). Moreover, the record is consistent with avoidance of Petitioner's dominant right arm (recognized in prior cases as a "reasonable request that vaccinated individuals often make." *Rizvi*, 2022 WL 2284311, at *4; *see also* Ex. 6 at 5 (indicating that Petitioner is right-handed). Thus, the contemporaneous, handwritten vaccine administration record in this case has some facial reliability that Petitioner has not undermined.

While a subsequent, PCP computerized record indicates a right-sided vaccine administration, that was not based on any medical provider's personal knowledge of what transpired at the retail pharmacy location. Rather, it was created later in time, and likely represents either the PCP's assumption, or Petitioner's own report of situs. It also lacks any context – such as Petitioner's complaints or any findings of a shoulder injury potentially attributable to vaccination at that time.

1870268, at *5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); *Stoliker v. Sec'y of Health & Human Servs.*, No. 17-0990V, 2018 WL 6718629, at *4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018).

[10] *See, e.g.*, *Schmidt v. Sec'y of Health & Hum. Servs.*, No. 17-1530V, 2021 WL 5226494, at *8 (Fed. Cl. Spec. Mstr. Oct. 7, 2021); *Marion v. Sec'y of Health & Hum. Servs.*, No. 19-0495V, 2020 WL 7054414 at *8 (Fed. Cl. Spec. Mstr. Oct. 27, 2020).

The subsequent medical records, beginning roughly four months post-vaccination, are consistent with Petitioner's contentions that the vaccine was administered in her right shoulder. But that belief is weakly supported by the available non-medical documentation, which indicates that Petitioner complained to Walgreens and was referred to its claims examiner by eight months post-vaccination, leading to her discovery of the Vaccine Program by nine and one-half months post-vaccination.[11] Such evidence, "no matter how sincere, is not sufficient to meet her burden of proof," Response at 11, particularly in the face of the contemporaneous handwritten record compelling a different result. I therefore find that the vaccine was more likely than not administered in Petitioner's left deltoid.[12]

Conclusion and Order to Show Cause

The factual finding of a left-sided vaccine administration renders the claim of a right-sided SIRVA untenable. *See* 42 C.F.R. § 100.3(c)(10)(iii) (providing that a SIRVA is limited to "the shoulder in which the intramuscular vaccine was administered"). Petitioner's Table SIRVA claim is therefore **DISMISSED.**

It is therefore unnecessary to resolve whether Petitioner's shoulder pain began within the 48-hour post-vaccination timeframe that would be required for a Table SIRVA claim. 42 C.F.R. §§ 100.3(a), (c)(10)(ii); Rule 4(c) Report at 7, Response at 10 - 14 (challenging this criteria).

Instead at this stage, the remaining question is whether any off-Table, causation-in-fact claim might be feasible. *See generally* Petition (alleging only a Table SIRVA); *but see* Brief at 3 (requesting the opportunity to pursue causation-in-fact); *but see* Rule 4(c) Report at 7 – 8, Response at 15 - 17 (averring that Petitioner's treating providers did not endorse a vaccine injury). Respondent's briefing and my preliminary review of the evidence has not identified any obvious onset date, or alternative cause, for the injury

[11] But the available non-medical evidence is notably sparse – in particular, lacking any contemporaneous documentation or later recollections of the timing, or substance, of Petitioner's complaints directly to Walgreens prior to being referred to its claims administrator Sedgwick. This stands in contrast to Petitioner's contemporaneous documentation of concern, and prompt action, regarding her insurance provider's potential overpayment to Walgreens for the vaccination.

[12] Petitioner (and Respondent) received a full and fair opportunity to present her case – including an opportunity to file any additional evidence in conjunction with the briefing. Scheduling Order filed July 26, 2022 (ECF No. 26).

It is also recognized that Petitioner had "no objection" to a hearing. Brief at 1. But Petitioner herself seemingly would have been the only witness to testify, based on the lack of affidavits from any other witnesses. Thus, I find it appropriate to resolve the claim on the filed record. Section 12(d)(2)(D); Vaccine Rule 8(d); *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (affirming the decision to rule on the record in lieu of hearing).

discussed herein. Therefore, Petitioner will be afforded one brief and final opportunity to determine whether she would like to pursue any remaining causation-in-fact claim centering on an injury in the non-vaccinated shoulder/arm. However, it is reiterated that Petitioner may not formally retain an expert, or order any expert's written report, without prior consultation with Respondent and the Court. Any request for experts, when combined with this case's age, would likely support the case's transfer out of SPU for further proceedings.

Petitioner's failure to respond to this or other orders issued in this action, as well as failure to file evidence required to support his claim, will be interpreted as a failure to prosecute resulting in dismissal of Petitioner's claim. *Tsekouras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 439 (1992), *aff'd*, 991 F.2d 810 (Fed. Cir. 1993) (per curiam); *Sapharas v. Sec'y of Health & Hum. Servs.*, 35 Fed. Cl. 503 (1996); Vaccine Rule 21(b).

Accordingly, within 30 days, by no later than Monday, July 8, 2024, Petitioner shall show cause why her claim should not be dismissed for insufficient proof of causation-in-fact.

In the alternative, if Petitioner wishes to exit the Vaccine Program, counsel shall file the appropriate motion, Stipulation, or Notice. *See* http://www.uscfc.uscourts.gov/sites/default/files/autism/EXITING_GUIDANCE_TO_PRO_SES.pdf.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master